Analytical Methods for Walking on the Lawful Side of Sugars, Dietary Fiber and Bioactive Sweeteners

David W. Plank
Managing Principal, WRSS
Senior Research Fellow,
Dept. of Food Science and Nutrition,
University of Minnesota
October 23, 2018
Introduction: Dave Plank

- Managing Principle of WRSS-Food & Nutrition Insights
- Senior Research Fellow, Dept. of Food Science and Nutrition, U of M
- Formerly, Medallion Labs Senior Technical Manager
  - Division of General Mills, Inc.
  - Nutrition labeling of food products
- Research areas:
  - Dietary Fiber
  - Protein Quality
  - Trans fat replacement technology
  - Enzyme analysis methodologies
  - Analytical method development
General Services:

- Product design and development
- Product Labeling and Regulatory
- Intellectual Property Creation and Assignment
- Shelf-life solutions
- Citizen Petitions
- Self-GRAS and FDA notified GRAS
- Population exposure studies
- Prop 65 Defense and Solutions
- Defense of class action lawsuits
Overview:
Sugars, Dietary Fiber and Bioactive Sweeteners

- Intent of new FDA regulations
- Why Class-action risk should be considered first
- New definition of dietary fiber
- Dietary fibers sweeteners
- Definition of sugars versus fiber
- Bioactive sugar opportunities
- Analytical methods for labeling NDC
- Changes and opportunities in counting calories
Intent of new FDA regulations: Added Sugar

- Make added sugar “transparent” for the public
- Discourage food manufacturers from adding sugar
- Improve health of US population
  - Maintain healthy weight
  - Reduce cardiovascular disease risk
Eliminate “Fake” fiber from labels and
- restore consumer confidence in dietary fiber labeling.
- demonstrate true health benefits for claimed fiber.

Encourage consumption of
- more dietary fiber by US population.
- more intrinsic whole-grain/whole-food fiber.
Dietary Fiber Consumption Falls Short for Many Countries

25 g to 40 g dietary fiber per day recommended

Avoiding Class Action Lawsuits

• The basis of complaint for nearly all food class actions:
  – deliberately misleading average consumers through labeling.
    • best not to be overly clever
    • best to be transparent
    • do not try to game the system
  – Why?
    • Competitors will want to eliminate your advantage if they can’t duplicate.
    • Attorneys/consumers are looking for a pay day – unique labels and technologies stand out and are scrutinized.

• Potential warning sign that a labeling or formulation strategy could lead to Class Action:
  – strategy defeats the intent of the FDA labeling rule
New Definition of Dietary Fiber

Two Classes of Dietary Fiber:

1. Non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units), and lignin that are INTRINSIC AND INTACT in plants;

2. ISOLATED OR SYNTHETIC non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health.

21 CFR 101.9(c)(6)(i)
Isolated and Synthetic NDC must demonstrate a physiological benefit to health

- Lower Blood Pressure
- Lower Cholesterol
- Lower Triglycerides
- Reduced Glycemic Response
- Mineral uptake/retention
- Satiety
- Laxation
- Weight Loss
Two Classes of Dietary Fiber:

1. INTRINSIC AND INTACT
   - Self-determined by Food Manufacturer
   - Due diligence concurrence with Ingredient supplier determination

2. ISOLATED OR SYNTHETIC
   - Determined by FDA based on a Citizen Petition
Elements of Intrinsic and Intact Fiber

Must be traditionally consumed by the U.S. Population

- **INTRINSIC** = originating and included wholly within a food;
- **INTACT** = no relevant component removed or destroyed; thus
- **INTRINSIC AND INTACT DIETARY FIBERS** ~ Contain all of the same relevant components found in the whole plant.

Any Analytical method which measures nutrients and bioactives in a food product can be used to contribute to evidence for Intrinsic and Intact.
Establishing retention of three dimensional structure by microscopy
Recommendation for determination of Intrinsic and Intact Fiber

- Form of an independent panel of non-employee, experts
  - Similar to traditional GRAS panel
  - Experts without conflicts of interest
  - Review
    - manufacturing process
    - analytical data pre- and post- process
    - traditional US consumption data

- Documentation benefits
  - class action challenge
  - FDA enforcement action

- Drawbacks
  - No official list of I & I for independent verification
Isolated or Synthetic Dietary Fiber

- Published list by FDA

**Original:**
1. [beta]-glucan
2. psyllium husk
3. cellulose;
4. guar gum;
5. pectin;
6. locust bean gum; and
7. hydroxypropylmethylcellulose.

**Recently added:**
8. mixed plant cell wall fibers;
   - cellulose;
   - pectin;
   - lignin;
   - beta-glucan; and
   - arabinoxylan
9. arabinoxylan;
10. alginate;
11. inulin and inulin-type fructans;*
12. high amylose starch (resistant starch 2);
13. galacto-oligosaccharide;*
14. polydextrose; and
15. resistant maltodextrin/dextrin.

*Use the appropriate AOAC Method for the specific fiber type.
Inulin is a mixture of fructose polymers that varies from DP3 to DP60.

Inulin is extracted from: chicory root, agave, and Jerusalem artichoke.

Inulin may be hydrolyzed to shorter DP enzymatically.

Short-chain fructo-oligosaccharides (scFOS) can be manufactured from sucrose and fructose by an enzymatic process (DP2 – DP4).

Inulin is not digested by human enzymes in the small intestine and fermented in the colon.

Physiological benefit: bone mineral density and absorption of calcium.
Short-Chain FOS can deliver 30-60% of the sweetness of sucrose

 Sucrose (DP2)  1- Kestose (DP3)  Nystose (DP4)  Fructofuranosynystose (DP5)

AOAC Official Method 997.08
Fructans in Food Products
Ion Exchange Chromatographic Method
First Action 1997
Final Action 1999
(Applicable to the determination of added fructans in processed foods.)

Are the mono and disaccharides in fiber added sugar?

Likely no* -

• If the fiber does not explicitly fall within the scope of the “Added Sugars” definition

• If the fiber is distinguishable from both:
  1. Fruit and vegetable products considered “Added Sugars”; and
  2. Sugar syrups purposely created through hydrolysis (enzymatic or chemical)

• If the ingredient primarily consist of fiber, a critical nutrient

• If the level of sugar does not exceed the natural level in the source material from which the fiber is derived.

© 2018 WRSS

*Based on Covington and Burling Opinion provided by Sensus via Claudia O’Donnell
Galacto-oligosaccharides (GOS)

- GOS is produced by the enzymatic treatment of lactose to produce oligosaccharides
- Typically DP₂ – DP₈
- Physiological benefit: Increases calcium absorption in the gut
- Approximately 40% the sweetness of sucrose
FDA definition of Sugars

- FDA defines Monosaccharides (DP1) and Disaccharides (DP2) as sugars.
  - existed before new rules and will continue.
- FDA sugar definition based on chemical structure and not physiological benefits.

Example:
- D-tagatose (92% the sweetness of sucrose)
- Isomaltulose (42% the sweetness of sucrose)
- Existing Health claim: D-tagatose and isomaltulose may reduce the risk of dental caries (tooth decay).
- FDA: D-tagatose and isomaltulose are chemically sugars.
Bioactive Sweeteners: Allulose

- Monosaccharide
- Stereo chemical isomer of fructose (3-position)
- 70% of the sweetness of sucrose
- 0 to 0.4 calories per gram
- Inhibits intestinal alpha-glucosidase
- Physiological benefit of Fiber: Glycemic response reduction
  - Reduced digestion of co-consumed starch!
- Citizen petition on labeling still pending
Allulose Analysis (AOAC 977.20 with modifications)

Erythritol

Allulose
Appropriate methods for determination of Dietary Fiber

Which AOAC dietary fiber methods may be used for declaring dietary fiber after Jan. 2020?

Answer: None

The traditional AOAC Methods only measure Non-digestible Carbohydrates under the new rule.
FDA recommended Analytical Methods for determining Non-digestible Carbohydrates (NDC)

• Use:
  – AOAC 2009.01
  – AOAC 2011.25
  – an equivalent AOAC method of analysis.

• Subtract the amount of NDC added which do not meet fiber definition.

• Manufacturers must keep written records of NDC added to product which does not meet fiber definition.

§ 101.9(c)(6)(i)
Current Dietary Fiber Methods

Prosky Method
AOAC 985.29

Lee Method
AOAC 991.43

CODEX Definition
AOAC 2009.01
AOAC 2011.25

McCleary Methods
Includes HPLC for DP>3 to ~40

Gravimetric
Insoluble Fiber & Soluble Fiber

AOAC 2001.03
Recovers HPLC for DP>3 to ~40
Difference in Total TDF for RS2 and RS4 Starches

AOAC 991.43 versus AOAC 2009.01

![Bar chart showing the difference in TDF for RS4 Wheat Starch Fibersym and RS2 Corn Starch Hi-Maize 260 between AOAC 991.43 and AOAC 2009.01 standards.](image-url)
Inactivation of “Heat Stable” Alpha Amylase

Alpha Amylase Activity measured by AOAC 2002.01 Ceralpha Assay

4-parameter Hill Plot fit:

\[ y = \frac{\text{min} + (\text{max} - \text{min})}{(x / \text{IC50})^\text{Hillslope}} \]

Time (min)

Activity (%)

0 10 20 30 40
0 20 40 60 80 100 120

AOAC 985.29 @ 95°C
R-square = 0.986
IC50 = 14 min

25°C Controls

Malate Ctrl @ 95°C
R-square = 0.986
IC50 = 22 min

AOAC 991.43 @ 95°C
R-square = 0.995
IC50 = 21 min

AOAC 985.29 @ 95°C
R-square = 0.998
IC50 = 14 min
New Rapid Integrated Dietary Fiber Method Addresses Resistant Starch Artifacts

McCleary Methods

CODEX Definition

AOAC 2009.01

AOAC 2011.25

AOAC 2017.16 RINTDF

Includes HPLC for DP>3 to ~40

Only TDF Collaborative Study to Date

RINTDF currently does not measure insoluble/soluble portions
Improved Recovery of RS by AOAC 2017.16

For most other matrices, AOAC 2017.16 = AOAC 2009.01 for quantification
AOAC 2011.25 or equivalent required if claiming alternative calories for dietary fiber

• Only AOAC 2011.25 allows
  – Insoluble NDC = 0 kcal/g; and
  – Soluble NDC = 2 kcal/g.

• Measuring TDF by AOAC 2009.01 gives
  – Total NDC = 4 kcal/g.

§ 101.9(c)(1)(i)(C)
Use of Alternative Caloric Values for Soluble Dietary Fiber (SDF)

• Previously a common practice
  – 1.5 Cal/g commonly used for inulin
  – Due to net carbs confusion, some manufacturers used Zero Cal/g for SDF!

• FDA will allow exceptions to 2 Cal/g for SDF only:
  – when the difference in energy value is significant; and
  – when evidence is established by science.

• FDA will evaluate exceptions on a case by case basis through the Citizen Petition process.

Example:
Polydextrose = 1 Calorie/gram
Summary

• The overall intent of the new regulations:
  – Make “added sugar” more transparent to the consumer
  – Assure consumers that dietary fibers are not “fake”
  – Improve the health of the US population

• A red-flag for class action risk is if a labeling strategy undermines the intent of the regulations.

• New dietary fiber definition:
  – Identifies approved fibers that may be used as sweeteners
  – Includes low-calorie opportunities for dietary fiber in product development

• Bioactive sugars may provide opportunities for delivering healthier products.
Thank You for your time!

Questions?
Appendix
Speaker Contact Information

David W. Plank
Managing Principal
WRSS Food & Nutrition Insights
37660 Reed Avenue
Taylors Falls, MN, USA 55084-1722
Ph. +1-952-818-7909
Email: dave.plank@wildriversoundstudio.com

David W. Plank
Senior Research Fellow
Dept. of Food Science and Nutrition
University of Minnesota
Room 225, FScN, 6099A
1334 Eckles Ave
St Paul, MN 55108
Phone: +1-952-818-7909
Email: plank003@umn.edu

© 2018 WRSS